

CERTIFICATE UNDER 37 CFR § 1.10 OF MAILING BY "EXPRESS MAIL"

The Examiner rejected claims 1-24 and 41-63 under 35 U.S.C. §112, second paragraph, as allegedly indefinite. Office Action at page 2, Item No. 2. Specifically, the Examiner stated that claims 1, 3, 4, and 41 are vague and indefinite for recitation of the term "substantially." *Id.*, lines 9-10.

The term "substantially" in claims 1, 3, 4, and 41 is used in the phrases "substantially neutralizing the cationic surfactant" and "substantially neutralizes the cationic surfactant." The Applicants respectfully point out that the term "substantially neutralizing" a cationic surfactant is specifically defined, for example, in the specification at pages 20-21, paragraphs 62 and 63. The specification states that "the term 'substantially neutralizing' the cationic surfactant, for the purposes of this application, means that more nucleic acid in a sample is capable of binding a solid phase application with such substantial neutralization than without the neutralization." Specification, page 20, lines 12-16.

Thus, the term "substantially" is well defined with respect to claims 1, 3, 4, and 41. The Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph.

#### Rejection Under 35 U.S.C. § 102(e)

The Examiner rejected claims 1-6, 9, 10, 14-17, 22-27, 30-33, 38-47, 52-55, 59, 60, and 64 under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Pat. No. 6,242,188 to Dattagupta et al., ("Dattagupta"). Office Action at pages 3 to 6, Item No. 4.

The Examiner stated that Dattagupta "describes compositions and methods for releasing nucleic acids from cells in a form that is suitable for labeling/capture, amplification, or detection in a single reagent addition step" and which include "a lipid,

membrane fluidizing compound, enzyme for degrading cell structure, metal chelators, or one or more nucleic acid probes or primers complementary to the nucleic acid to be detected." Office Action at page 3, lines 6 to 10.

Applicant respectfully traverses the rejection. For a reference to anticipate the claimed invention under 35 U.S.C. § 102, the reference must describe the invention such that "each and every limitation is found either expressly or inherently" within it. *Transclean Corp. v. Bridgewood Services, Inc.*, 290 F.3d 1364, 1370, 62 USPQ2d 1865, 1869 (Fed. Cir. 2002) (citations omitted); see Manual of Patent Examining Procedure § 2131 (8<sup>th</sup> ed. 2001) ("MPEP") ("to anticipate a claim, the reference must teach every element of the claim").

Claim 1 of the present application recites a method for releasing nucleic acids from a biological sample that comprises the step of binding nucleic acid to a solid phase. Claims 2-6, 9, 10, 14-17, 22-27, 30-33, and 38-40 all ultimately depend from claim 1.

Applicants note that the Examiner failed to state that Dattagupta teaches a method for obtaining nucleic acid from a biological sample that comprises binding the nucleic acid to a solid phase.

Claim 41 of the present application recites a kit comprising a protease, a cationic surfactant, and a second surfactant, wherein the second surfactant substantially neutralizes the cationic surfactant. Claims 42-47, 52-55, 59, and 60 all ultimately depend from claim 41. Claims 64 recites a kit comprising a protease, a cationic surfactant, a non-ionic surfactant that permits the binding of nucleic acid to a solid

FINNEGAN  
HENDERSON  
FARABOW  
GARRETT &  
DUNNER LLP

1300 I Street, NW  
Washington, DC 20005  
202.408.4000  
Fax 202.408.4400  
www.finnegan.com

phase in the presence of the protease and cationic surfactant, and a buffer with a high salt concentration.

At the outset, Applicant notes that the Examiner failed to cite a particular section of Dattagupta that she considered to teach a composition for releasing nucleic acids from a sample comprising a cationic surfactant. The Examiner also failed to cite a particular section of Dattagupta that she considered to teach a composition for releasing nucleic acids from a sample comprising a second surfactant that substantially neutralizes the cationic surfactant.

As the Examiner stated, Dattagupta discusses cationic surfactants as only being useful in liposome preparations for the "removal of surfactant approach." Dattagupta, column 6, lines 57-65. In that approach, the cationic surfactants must be removed by filtration or dialysis. *Id.*, and Office Action, page 6, lines 12-17. In fact, the cationic surfactant is removed from the solution before the composition of Dattagupta is exposed to a biological sample. Dattagupta, col. 6, lines 64-65; and Office Action, page 6, lines 17-18. Thus, Dattagupta does not teach a composition for releasing nucleic acids from a biological sample comprising a cationic surfactant. Accordingly, the Examiner fails to establish that Dattagupta anticipates claims 41-47, 52-55, 59, 60, and 64.

For at least the reason presented above, the Examiner has failed to establish that Dattagupta would have anticipated claims 1-6, 9, 10, 14-17, 22-27, 30-33, 38-47, 52-55, 59, 60, and 64. Thus, Applicant need not address the Examiner's contentions concerning other limitations of those claims at pages 2-6 of the Action. By not addressing those contentions, Applicant in no way acquiesces to those contentions.

Reconsideration and withdrawal of the §102 rejection is respectfully requested.

FINNEGAN  
HENDERSON  
FARABOW  
GARRETT &  
DUNNER LLP

1300 I Street, NW  
Washington, DC 20005  
202.408.4000  
Fax 202.408.4400  
www.finnegan.com

Rejection Under 35 U.S.C. § 103(a)

The Examiner rejected claims 1-64 under 35 U.S.C. § 103(a) as allegedly being obvious over Dattagupta in view of U.S. Pat. No. 5,130,423 to Van Ness et al. ("Van Ness"). Office Action, pages 6 to 8, Item No. 5.

The Examiner stated that Dattagupta teaches the use "compositions and methods for releasing nucleic acids from cells in a form that is suitable for labeling/capture, amplification, or detection in a single reagent addition step" and "compositions include[ing] a lipid, membrane fluidizing compound, enzyme for degrading cell structure, metal chelators, or one or more nucleic acid probes or primers complementary to the nucleic acid to be detected." Office Action, page 7, Item No. 6. The Examiner alleged that "it would have been obvious at the time the invention was [made] to [include a nuclease] inhibitor such as bentonite as taught by Van Ness for the method of Dattagupta." *Id.*, at page 8, lines 1-2. The Examiner further alleged that the motivation for the use of the nuclease inhibitor is to avoid the use of phenol or phenol/chloroform, thereby avoiding "hazardous waste" and a "time consuming and laborious" process. *Id.*, at page 8, lines 2-5. Applicant respectfully traverses the rejection.

As discussed above, Claim 1 recites in part a method for obtaining nucleic acids from a biological sample comprising binding the nucleic acid to a solid phase. All of the dependent claims 2-40 ultimately depend from claim 1, and thus include all of the limitations of claim 1. As discussed above, the Examiner failed to establish that Dattagupta teaches a method for obtaining nucleic acids from a biological sample comprising binding the nucleic acid to a solid phase. Examiner fails to assert, let alone

FINNEGAN  
HENDERSON  
FARABOW  
GARRETT &  
DUNNER LLP

1300 I Street, NW  
Washington, DC 20005  
202.408.4000  
Fax 202.408.4400  
www.finnegan.com

establish, that Dattagupta would have suggested such a method. Further, Van Ness does not teach and would not have suggested a method for obtaining nucleic acids comprising binding the nucleic acid to a solid phase.

As discussed above, Claims 41 and 64 recite in part a kit comprising a cationic surfactant. All of the dependent claims 42-63 ultimately depend from claim 41, and thus include all of the limitations of claim 41. As discussed above, the Examiner failed to establish that Dattagupta teaches a composition for releasing nucleic acids comprising a cationic surfactant. Moreover, the Examiner fails to assert, let alone establish that Dattagupta would have suggested such a composition. Further, Van Ness does not teach and would not have suggested a composition for releasing nucleic acids comprising a cationic surfactant.

Thus, the Examiner has failed to establish that the combination of Dattagupta and Van Ness would have rendered obvious any of the rejected claims. Moreover, applicant need not address the Examiner's contentions concerning the combination of Dattagupta and Van Ness with respect to other limitations of certain dependent claims. By not addressing those contentions, Applicant in no way acquiesces to those contentions.

Applicant respectfully requests reconsideration and withdrawal of the § 103 rejections of claims 1-64 in view of Dattagupta and Van Ness.

### Conclusion

Applicant respectfully asserts that the application is in condition for allowance. If the Examiner does not consider the application to be in condition for allowance,

Applicant requests that the Examiner call the undersigned ((650) 849-6676) to arrange an interview prior to taking action.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: October 25, 2002

By: *Robert W. Mann*  
Robert W. Mann  
Reg. No. 48,555

FINNEGAN  
HENDERSON  
FARABOW  
GARRETT &  
DUNNER LLP

1300 I Street, NW  
Washington, DC 20005  
202.408.4000  
Fax 202.408.4400  
www.finnegan.com